

Exhibit E

Peggy Pence, Ph.D.

1 UNITED STATES DISTRICT COURT
 2 SOUTHERN DISTRICT OF WEST VIRGINIA
 3 AT CHARLESTON
 4
 5 IN RE: ETHICON, INC., PELVIC) Master File No. 2:12-MD-02327
 REPAIR SYSTEM PRODUCTS) MDL No. 2327
 6 LIABILITY LITIGATION)

7
 THIS DOCUMENT RELATES TO) Joseph R. Goodwin
 8 CAROLYN LEWIS, ET AL. v.) U.S. District Judge
 ETHICON, INC.)
 9 Case No. 2:12-CV-04301)

10
 11
 12 - - - - -
 13 NOVEMBER 12, 2013
 14 - - - - -
 15

16 Deposition of PEGGY PENCE, Ph.D., RAC, FRAPS,
 17 VOLUME I, held at Hyatt Westlake Village, 880 South
 18 Westlake Boulevard, Westlake Village, California,
 19 beginning at 9:10 a.m., on the above date, before
 20 Kimberly S. Thrall, a Registered Professional Reporter
 21 and Certified Shorthand Reporter.

22
 23
 24 Golkow Technologies, Inc.
 877.370.3377 ph | 917.591.5672 fax
 25 deps@golkow.com

1 Ethicon.

2 Q. Okay. So these were MDR issue reports?

3 A. They're complaints.

4 Q. Complaints?

5 A. Yeah. They're -- the issue report is the
6 document on which Ethicon records complaints and its
7 investigation of complaints and whether or not they are
8 reportable to governmental agencies, FDA or in the case
9 of Europe, for example, the European authorities.

10 Q. On page 98, I think you say there were 862 TVT
11 issue reports received and reviewed for this report?

12 A. Yes.

13 Q. Okay. 258 were determined not to be
14 reportable?

15 A. Yes. Approximately 30 percent of those that we
16 received were not reportable, according to Ethicon.

17 Q. Exhibit 3 has 29 AEs that were not reported?

18 A. Yes. Those are, as I said, examples.

19 Q. Does Exhibit 3 contain all of the issue reports
20 that you believe Ethicon should have reported to the FDA
21 for a serious injury definition?

22 A. It's not -- it's not a comprehensive
23 compilation. It's representative examples.

24 Q. Do you have the other ones that you -- let me
25 ask you this: Do you intend to come to trial and say

1 A. So that's why I'm saying I'd have to go back
2 and look at every MDR for any mesh product to see if FDA
3 knew about it before or not, if we're talking about
4 specific -- any specific adverse event, if I understand
5 your question correctly.

6 Q. You did.

7 With regard to the TVT issue reports that you
8 believe were not submitted --

9 A. But should have been.

10 Q. -- but should have been, I mean, that's a given
11 in the question. Let me just redo the question, then.

12 With regard to the TVT issue reports that you
13 believe were not -- strike that. I see. You corrected
14 me.

15 With regard to the TVT issue reports which you
16 believe should have been reported, okay, do they impact
17 the overall risk/benefit analysis of the TVT device?

18 MR. KUNTZ: Objection.

19 THE WITNESS: There are a couple of points to
20 be made with regard to that. The regulation requires
21 that all adverse events that made a certain definition
22 be reported to the FDA. The purpose of that is so that
23 the FDA can have a complete picture and if -- of the
24 true safety profile of products. We already know
25 there's underreporting. And in this case, there's

Peggy Pence, Ph.D.

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA
3 AT CHARLESTON

4
5 IN RE: ETHICON, INC., PELVIC) Master File No. 2:12-MD-02327
REPAIR SYSTEM PRODUCTS) MDL No. 2327
6 LIABILITY LITIGATION)

7
THIS DOCUMENT RELATES TO) Joseph R. Goodwin
8 CAROLYN LEWIS, ET AL. v.) U.S. District Judge
ETHICON, INC.)
9 Case No. 2:12-CV-04301)

10

11

12 - - - - -

13 NOVEMBER 13, 2013

14 - - - - -

15

16 Deposition of PEGGY PENCE, Ph.D., RAC, FRAPS,
17 VOLUME II, held at Hyatt Westlake Village, 880 South
18 Westlake Boulevard, Westlake Village, California,
19 beginning at 10:16 a.m., on the above date, before
20 Kimberly S. Thrall, a Registered Professional Reporter
21 and Certified Shorthand Reporter.

22

23

24 Golkow Technologies, Inc.

877.370.3377 ph | 917.591.5672 fax

25

deps@golkow.com

1 Let me ask you this: With regard to medical
2 devices, have you ever had to review adverse event data
3 and make determinations whether MDR reports should be
4 submitted to the FDA?

5 A. Yes.

6 Q. Okay. And when did you have that experience?

7 A. As recently as within the last year.

8 Q. Did your experience in reviewing MDR reports
9 ever include surgical mesh?

10 A. No. But the same principles apply.

11 Q. Did your experience ever involve reviewing
12 adverse event data on a device used to treat stress
13 urinary incontinence?

14 A. No.

15 Q. Did you individually look at medical
16 information, including the MDR report and any follow-up
17 information you may have seen, and then make your own
18 medical judgment based on your review of the matter
19 whether the MDR should be submitted to the FDA?

20 A. I think I understood that question, but it was
21 lengthy. Could I just have you repeat it back, please.

22 MR. SNELL: I'll ask the court reporter to, if
23 that's okay with you.

24 THE COURT REPORTER: Of course.

25 (The following record was read by the reporter:

1 "Q. Did you individually look at medical
2 information, including the MDR report and any
3 follow-up information you may have seen, and
4 then make your own medical judgment based on
5 your review of the matter whether the MDR
6 should be submitted to the FDA?")

7 THE WITNESS: Let me just clarify a little bit
8 of the language. The MDR reports and maybe -- let me
9 ask you, do you mean the issue reports instead of MDR
10 reports? Because MDR reports would have already been
11 submitted to the FDA.

12 BY MR. SNELL:

13 Q. I'm sorry. The issue reports.

14 A. Issue reports. Okay.

15 So, yes, as we discussed yesterday, the issue
16 reports, I have reviewed issue reports which were not
17 reportable and, in fact, you know, as we talked about
18 yesterday, I have examples in my report and the exhibits
19 attached to my report of issue reports that I did review
20 and based on my review of those issue reports determined
21 that they should have been reported to the FDA as MDR
22 reports.

23 Q. You're not a doctor or a surgeon, so you didn't
24 exercise medical judgment, did you?

25 A. I exercised -- if you look at the regulations

1 and you look at the types of individuals that FDA
2 considers qualified to review issue reports and
3 determine -- or complaints and determine whether or not
4 they qualify as MDR reports, that includes not only
5 physicians, but nurses, risk managers and biomedical
6 engineers. I have functioned in the capacity of a risk
7 manager for review of medical -- of adverse event
8 reports for years and years of my career and I applied
9 in making my determinations of the reportability of
10 these issue reports that we've -- that we discussed
11 yesterday.

12 And the ones that are in my report, I applied
13 the same standard of practice that I do on a daily basis
14 in execution of my responsibilities for the clients with
15 whom I work.

16 Q. But you didn't use medical judgment, did you?

17 MR. FREESE: Object to the form of the
18 question.

19 THE WITNESS: You don't have to be --

20 BY MR. SNELL:

21 Q. I'm sorry. It's a yes-or-no question.

22 MR. FREESE: Object to the form of the question
23 anyway.

24 THE WITNESS: I used my -- my medical knowledge
25 as a toxicologist and a clinical development regulatory

Peggy Pence, Ph.D.

1 scientist and applied that in the context of the
2 regulations. I'm not a doctor. So in that sense, I
3 didn't apply a physician's knowledge, but I applied the
4 knowledge in the fashion that I mentioned.

5 BY MR. SNELL:

6 Q. Have you reviewed any of the attorney
7 advertising that pertains to TVT in connection with your
8 expert report?

9 A. Attorney advertising?

10 Q. Yes.

11 A. No.

12 Q. Did you ever ask counsel for any of the Lewis
13 case-specific materials, such as her medical records and
14 her depositions?

15 A. No, I did not. I did ask the date of the
16 surgery and, you know, general information, but not for
17 specific records.

18 MR. SNELL: Let's go off the record for a
19 second.

20 (Brief recess.)

21 MR. SNELL: Let's go back on.

22 BY MR. SNELL:

23 Q. You looked at the IFU for TVT, correct?

24 A. Yes.

25 Q. Okay.

Peggy Pence, Ph.D.

1 A. Multiple IFUs.

2 Q. Right. Did you look at the IFUs across all
3 other products to treat incontinence or prolapse that
4 are mesh products?

5 A. Across other manufacturers' --

6 Q. Yeah. I --

7 A. -- products? Certainly, as we talked
8 yesterday -- are you talking about SUI or are you
9 talking about POP?

10 Q. Well, we can start with SUI. So what other
11 IFUs for SUI products, if any, have you looked at?

12 A. I'm in the process of looking at some others at
13 the moment for SUI, but --

14 Q. The one you identified yesterday was the
15 Obtryx, Boston Scientific?

16 A. Boston Scientific, yes.

17 Q. And what about for prolapse meshes? Have you
18 looked at other manufacturers' IFUs, you know, like you
19 did with TVT across time in the different versions?

20 A. For the Bard Avaulta product.

21 Q. And I think your report identifies that there
22 are 80 or 90 mesh products in total that have been
23 510(k) cleared?

24 A. That's not the number of mesh products. I'm
25 sorry. That's the number of clearances, if I recall